

### **REMARKS**

In the Office Action dated October 12, 2005, the Examiner rejected all non-withdrawn, pending claims 1-4, 7-18, 23, 24, 35, 36, 38-41, and 43. Claims 5, 6, 19-22, 37, and 42 had been previously withdrawn from consideration as a result of Applicant's species election.

In response to the Office Action, Applicant has amended claims 1, 7, 8, 10, 14, and 15, and added new claims 44-47. Consequently, claims 1-25 and 35-47 are pending, but of those claims 5-6, 19-22, 37, and 42 are presently withdrawn from consideration.

In view of the amendments to the claims and the following remarks, Applicant requests reconsideration of the patentability of rejected claims 1-4, 7-18, 23, 24, 35, 36, 38-41, and 43; asks that the Examiner consider newly added claims 44-47; and asks that the Examiner consider, pursuant to 37 C.F.R. 1.141, the patentability of withdrawn claims 5, 6, 19-22, 37, and 42 as being in dependent form and including all the limitations of an allowed generic claim. Applicant also asks that the Examiner review the references submitted in the Supplemental Information Disclosure Statement filed December 30, 2005.

### **Examiner Interview Summary**

Applicant's attorney would like to thank the Examiner for the telephone interview conducted on January 4, 2006. Attendees were Stephen Schaefer and William Woodford for the Applicant, and Examiner Johnson. During the interview, the Examiner's outstanding rejection and the Body et al. reference were discussed.

### **Claim Rejections – 35 U.S.C. § 102**

#### **Independent Claims 1, 10, and their dependents**

The Examiner rejected claims 1-4, and 7-17 (of which claims 1 and 10 are independent) under 35 U.S.C. § 102 as being anticipated by U.S. Patent 5,799,661 to Boyd et al. In particular, although the Examiner previously found that Boyd et al. did not anticipate claims 1 and 10, the Examiner stated that "[u]pon reconsideration, the apparatus of Boyd et al. is clearly capable of

being inserted into a body vessel and is deployable longitudinally,” and found claims 1 and 10 anticipated by Boyd et al.

While not conceding the correctness of the Examiner's position, to advance prosecution, Applicant has amended independent claims 1 and 10 to recite more particularly structural features that distinguish Boyd et al., namely, that the claimed device's elongate body distal end is “sized and adapted to enter into a body blood vessel.” Support for this amendment appears in Applicant's specification as originally filed, for example, in Figures 1-5 and the accompanying text. Thus, the amendments add no new matter.

Applicant submits that independent claims 1 and 10, as amended, define subject matter that is patentable over Boyd et al. Claim 1 is directed to a medical device that comprises an elongate body having a distal end sized and adapted to enter into a body blood vessel and positionable near a target tissue region within the body. The medical device also comprises a structure longitudinally deployable from the distal end of the elongate body to cool the target tissue region. Claim 10 is also directed to a medical device and has several limitations in common with claim 1.

Boyd et al. discloses devices and methods for performing port-access or closed-chest coronary artery bypass surgery, including a topical hypothermia device or use during a port-access bypass procedure. The topical hypothermia device has a flexible heat exchanger that is collapsible into a pre-deployed position to fit through an access port made in the chest of the patient. According to Boyd et al., the topical hypothermia device has a short tubular shaft made of rigid material, such as stainless steel or a hard plastic. The outer sheath of the device (Fig. 42, #239) is sized to fit through an access cannula with a 10-12 mm internal diameter. Because the Boyd et al. device is intended to pass through a short access cannula, the device is short, has a rigid shaft, and a relatively large outer diameter.

Boyd et al. does not disclose the subject matter of either of Applicant's claim 1 or claim 10. In particular, Boyd et al. does not disclose a medical device comprising an elongate body having a distal end that is sized and adapted to enter into a body blood vessel. Indeed, the distal

end of the Boyd et al. device is not sized and adapted to enter into a body blood vessel, as discussed above. Therefore, Boyd et al. does not anticipate claims 1 and 10.

Nor does the Boyd et al. reference, either alone or in combination with other references, render either of claims 1 or 10 obvious. In particular, the devices of claims 1 and 10 are new structures that are optimally suited for an important new application of cooling tissue within a heart chamber when blood flow to the heart chamber is temporarily reduced or entirely blocked (so as to reduce reperfusion injury after normal blood flow resumes), which is an application that is not even contemplated by Boyd et al. or any other prior art reference at issue. For example, as described in Applicant's specification at page 10, line 19, through page 12, line 25, Applicant's device has an elongate body with a distal end suitable for entry into a body blood vessel and positionable, for example, within a heart chamber. Once positioned, the deployable structure may be longitudinally deployed from a distal end of the elongate body to cool a target tissue region within the heart chamber. As such, the claimed devices permit the targeted cooling, by direct contact, of tissue located inside a heart chamber.

By contrast, the Boyd et al. device does not cool target tissue regions accessed via body blood vessels, but rather has a structure that cools the outside of the heart through an invasive procedure that requires the formation of a hole in the patient's chest. In addition, the size and structure of the Boyd et al. device is suitable for topical cooling applications and does not even suggest a structure that may be used for internal cooling of vessels and organs, such as cooling tissue inside a heart chamber. Due to the structural constraints of Boyd et al., one of skill in the art would not look to Boyd et al. for cooling where access via body blood vessels is required.

Accordingly, Applicant requests that the Examiner remove his rejection of independent claims 1 and 10 as being anticipated by Boyd et al., as well as the rejections to corresponding dependent claims 2-4, 8-9, and 11-17.

### **Claim Rejections – 35 U.S.C. § 103**

#### **Dependent Claims 18, 23, and 24**

The Examiner also rejected several of the claims depending from claim 10 as being unpatentable under 35 U.S.C. § 103(a). The rejection of each of these claims is based at least in part on Boyd et al. For the reasons discussed above, base independent claim 10 is patentable over Boyd et al., and the reasons the Examiner has given to reject the dependent claims do not overcome the deficiencies with respect to the base claim 10 discussed above.

Accordingly, Applicant asks that the Examiner remove his obviousness rejection of dependent claims 18, 23, and 24.

#### **Independent Claims 35, 40, and their dependents**

The Examiner rejected claims 35, 36, 38-41, and 43 (of which claims 35 and 40 are independent) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,575,966 to Lane et al. in view of Boyd et al. Applicants submit that independent claims 35 and 40 each defines an invention that is patentable in view of Lane et al. and Boyd et al.

Independent claim 35 is directed to a method of cooling a target tissue region inside a body. The method comprises introducing into a body vessel a distal portion of a catheter having an elongate body and a structure longitudinally deployable from a distal end of the elongate body, positioning the distal portion of the catheter near the target tissue region, longitudinally deploying the deployable structure from the distal end of the elongate body, placing the deployed structure in contact with the target tissue region; and cooling the deployed structure to cool the target tissue region. Independent claim 40 is also directed to a method similar to that of claim 35, and further recites that the target tissue region is within a chamber of the heart.

The Examiner contended that Lane et al. discloses all of the limitations of claims 35 and 40, except that Lane et al. does not disclose longitudinal deployment. The Examiner nevertheless contended that Boyd et al. teaches longitudinal deployment, and in addition, contended that those skilled in the art would look to related work in the art. The Examiner further contended that therefore it would have been obvious to one having ordinary skill in the

art at the time the invention was made to use the longitudinal deployment of the cooling structure as taught by Boyd et al. in the methods of Lane et al. as an alternative to the balloon deployment.

Applicant disagrees with the Examiner. Lane et al. discloses a elongated catheter device with a distal balloon assembly adapted for endovascular insertion. Lane et al. further discloses that coolant injected through the device may, in different embodiments, directly cool tissue contacting the balloon. Applicant's discussion of Lane et al. should not be taken as an admission that Lane et al. is properly considered prior art under any subsection of 35 U.S.C. § 102.

Lane et al. in combination with Boyd et al. does not render either independent claim 35 or 40 obvious. As the Examiner has conceded, Lane et al. does not disclose or suggest a method of using a device that has a structure that is longitudinally deployable from a distal end of an elongate body of the device, as each of claims 35 and 40 require. To the contrary, the Lane et al. device's balloon, which the Examiner deemed to be the claimed deployable structure, is expandable radially at a distal portion of the catheter. Regardless of whether or not the balloon in the Lane et al. device can be considered to be deployable, the balloon in the Lane et al. device is not deployable longitudinally from a distal end of an elongate body, as each of claims 1, 35 and 40 require.

In addition, the catheter used in the methods of claims 35 and 40 is a new structure that is optimally suited for an important new application of cooling tissue within a heart chamber when blood flow to the heart chamber is temporarily reduced or entirely blocked (so as to reduce reperfusion injury after normal blood flow resumes), which is an application that is not even contemplated by Lane et al. or any other prior art reference at issue. By contrast, the balloon in the Lane et al. device is described as being used for freezing or cooling tissue on the inner surface of a cylindrical vessel, such as an artery. While perhaps theoretically possible to use the balloon catheter device of Lane et al. for cooling tissue within a heart chamber, Applicant's design is better than the Lane et al. design for such an application for at least two reasons. First, by having a structure that is deployable longitudinally from a distal end of an elongate body as with Applicant's design, as opposed to expanding radially from a distal portion of an elongate body, Applicant's design provides for a better contact between the device's cooling structure and

the tissue that needs to be cooled, as is described in Applicant's specification at page 11, line 25, through page 12, line 12. In addition, using a balloon surface to provide cryotherapy, as with the Lane et al. device, requires sufficiently high pressure to cause the balloon to expand radially so that the outer balloon surfaces contact the inner surface of the cylindrical vessel, whereas with Applicant's method, cooled fluid at a lower pressure may simply be routed through the deployed structure. As such, the potential of a balloon bursting under the pressure of the cryogenic fluid, which also acts to expand the balloon, is not present with Applicant's method.

Furthermore, Boyd et al. also does not provide a suggestion to modify the Lane et al. device to provide it with a cooling structure that is longitudinally deployable from a distal end of an elongate body, despite the Examiner's contentions to the contrary. Importantly, Boyd et al. does not suggest the important new application, discussed above, of cooling tissue that can only be accessed by a catheter, for example, within a heart chamber, when blood flow to the heart chamber is temporarily reduced or entirely blocked (so as to reduce reperfusion injury after normal blood flow resumes), which again is an application that falls within method claims 35 and 40. By contrast, the heat exchanger of the hypothermia device disclosed in Boyd et al. is intended for topical cooling of the entire tissue region on the underside of the heart (i.e., the outside surface of the heart), and is too large to be deployed inside the body. As such, only with the benefit of hindsight could it be said it would be obvious to combine two different references (namely, Lane et al. and Boyd et al.) to render obvious Applicant's claimed device (or method using the device), when, indeed, neither reference contemplates the methods that are the subject of Applicant's claims 35 and 40.

Accordingly, the Applicant requests that that the Examiner remove his rejection of independent claims 35 and 40, as well as his rejection of dependent claims 36, 38-39, 41, and 43.

#### **Newly Added Dependent Claims**

Applicant has added dependent claims 44-47 of which one claim corresponds to each of independent claims 1, 10, 35, and 40. The dependent claims for the devices of claims 1 and 10 recite that the distal end is sized to be entered into a femoral artery. Similarly, the dependent

claims for the methods of claims 35 and 40 recite that the distal portion of the catheter is introduced into a femoral artery. Support for this amendment appears in Applicant's specification, for example, in the discussion of Figure 5 at page 10, line 27 to page 11, line 1.

Applicant requests that the Examiner consider dependent claims 44-47 and, in view of the amendments and remarks relating to the patentability of independent claims 1, 10, 35, and 40 from which these claims depend, these claims are in condition for allowance.

#### **Request for Consideration of Non-Elected (Withdrawn) Dependent Claims**

Pursuant to 37 CFR 1.142(b), the Examiner withdrew claims 5-6, 19-22, 37, and 42 from consideration as being drawn to a non-elected invention. Claims 5-6 depend from claim 1, claims 19-22 depend either directly or indirectly from claim 10, claim 37 depends from claim 35, and claim 42 depends from claim 40. Because independent claims 1, 10, 35, and 40 are each generic and allowable, and the claims that depend from these generic claims including all of the limitations of the generic claims, Applicant contends that dependent claims 5-6, 19-22, 37, and 42 are entitled to consideration and allowance pursuant to 37 CFR 1.141. Accordingly, Applicant asks that the Examiner consider these claims.

#### **CONCLUSION**

Applicant submits that all pending claims 1-24 and 35-47 are in condition for allowance and respectfully requests that the Examiner issue a notice of allowance. In addition, Applicant asks that the Examiner consider references cited in a supplemental information disclosure statement filed December 30, 2005.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this

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paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

No fee is believed due. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

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